UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/491,896	01/24/00	DURING	M 102194-6

021125 HM22/0907
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EXAMINER	
O'LAUGHLIN,B	
ART UNIT	**PAPER NUMBER**
1647	6
DATE MAILED:	09/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/491,896	DURING, MATTHEW J.	
	Examiner	Art Unit	
	Bridget E. O'Laughlin-Bunner	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *24 January 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 22, 25-32, 36, 38-44, 54, 56-68, 70, 72-74 drawn to a method of treatment, improvement, or modification of a neurological disorder or protein comprising administering an amino acid vaccine comprising a therapeutically effective amount of antigen wherein the antigen elicits the production of antibodies in the circulatory system, classified in class 424, subclass 184.1.

II. Claims 1-12, 22, 25-32, 36, 38-44, 54, 56-68, 70, 72-74, drawn to a method of treatment, improvement, or modification of a neurological disorder or protein comprising administering a nucleic acid vaccine comprising a therapeutically effective amount of antigen wherein the antigen elicits the production of antibodies in the circulatory system, classified in class 514, subclass 44.

III. Claims 1-5, 13-24, 33-37, 45-54, 59-68 drawn to a method of treatment, improvement, or modification of a neurological disorder or protein comprising a composition of a therapeutically effective amount of an isolated antibody or antibody portion wherein the antibodies bind to and modify the function of a target protein, classified in class 514, subclass 2.

IV. Claims 70-71, 75-81, drawn to a composition comprising a therapeutically effective amount of an isolated antibody or an antibody portion, wherein the antibodies bind to and modify the function of a target protein in the central nervous system, classified in class 424, subclass 130.1.

V. Claims 70-74, drawn to a composition comprising a therapeutically effective amount of an antigen capable of eliciting the production of antibodies in the circulatory system, classified in class 424, subclass 184.1.

VI. Claims 82-85, drawn to a genetic vaccine comprising an antigen and a pharmaceutical carrier, classified in class 424, subclass 193.1.

Please note that claim 79 states "the method of claim 70, wherein...". Claim 79 is dependent upon claim 70 which teaches a product rather than a method. In this manner, claim 79 was also understood to refer to a product.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in a materially different process, such as a diagnostic assay or an immunopurification procedure. In the instant case, the methods claimed do not require the product claimed in invention IV. Products such as heat shock proteins or blood proteins can be used in invention III.

b. Inventions V and I/II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in a materially different process, such as an isolation or purification procedure of a receptor. In the instant case, the methods claimed do not require the

product in invention V. Products such as heat shock proteins or blood proteins can be used in inventions I/II.

c. Inventions IV, V, and VI are different products. Antibodies, antigens, and genetic vaccines are distinct with respect to their structure and function to such an extent that they differ in mode of action. For example, inventions IV and V are both proteins, but are structurally unique. Antibodies are produced as a result of the introduction of an antigen. Moreover, the proteins of inventions IV/V are unique from the genetic (DNA) vaccine of invention VI. DNA is made of a different composition than proteins (nucleic acids vs. amino acids). The DNA of invention VI can be used as a probe to detect a gene or as a template to make a protein.

d. Inventions I/II/III are different methods because they require different ingredients, process steps, and endpoints. These inventions require different ingredients and process steps to accomplish the use of vaccines, antibody compositions, and antigen compositions. Groups I/II/III are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of efficacy of amino acid vaccine therapy and of measurement of antibody levels, which is not required by the other inventions. Invention II requires search and consideration of efficacy of nucleic acid vaccine therapy and of measurement of antibody levels, which is not required by the other inventions. Invention III requires search and consideration of efficacy of therapy and of protein function modulation, which is not required by the other inventions.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of treatment or improvement of a neurological or neuroendocrine disorder, wherein the disorder is:

Ia. stroke

Ib. epilepsy

Ic. obesity

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-21, 24-35, 38-53, 56-69, and 72-85 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for treating a subject with a neurological disorder comprising a composition of a therapeutically effective amount of an isolated antibody or an antibody portion, wherein the antibody or antibody portion is selected from:

Id. monoclonal antibody
Ie. polyclonal antibody
If. recombinant antibody
Ig. chimeric antibody
Ih. humanized antibody
Ii. Fab fragment
Ij. F(ab')2 fragment
Ik. single chain Fv fragment
Il. anti-NMDA receptor antibody
Im. anti-NMDAR1 antibody
In. anti-GluR antibody
Io. anti-GluR4 antibody
Ip. anti-GluR6 antibody
Iq. anti-NK-1 antibody
Ir. anti-dopamine transporter antibody
Is. anti-glutamic acid decarboxylase antibody
It. anti-neuropeptide Y antibody
Iu. anti-galanin
Iv. anti-CART antibody
Iw. anti-orexin antibody
Ix. anti-TRH antibody
Iy. anti-leptan antibody
Iz. anti-CRH antibody
IIa. anti-POMC antibody

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

held to be allowable. Currently, claims 3-12, 24-32, 38-46, 55-61, 68-69, 72-76, and 82-85 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method or composition for the treatment or modification of a neurological disorder or protein, wherein the antigen, vaccine antigen, and target protein are:

IIb. neurotransmitters

IIc. neuroreceptors

IId. transporters

IIe. ion channels

IIf. signal transduction molecules

IIg. enzymes involved in the synthesis of neurotransmitters

IIh. enzymes involved in the degradation of neurotransmitters

IIi. growth factors

IIj. transcription factors

IIk. cell-surface molecules

IIl. NMDA receptor

IIm. NMDAR1

IIn. GluR receptor

IIo. neuropeptide Y

IIp. galanin

IIq. NK-1 receptor

IIr. dopamine transporter

IIs. glutamic acid decarboxylase

IIt. cocaine and amphetamine-regulated transcript (CART)

IIu. orexin

IIv. thyrotropin-releasing hormone (THR)

IIw. leptan

IIx. corticotropin-releasing hormone (CRH)

IIy. pro-opiomelanocortin (POMC)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-5, 9-21, 23, 29-35, 37, 41-44, 47-53, 55, 59-67, 71, and 77-81 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicant selects Inventions I-III, one species from the neurological disorder group must be chosen to be fully responsive.

If applicant selects Inventions I-III or IV, one species from the antibody group must be chosen to be fully responsive.

If applicant selects Inventions I-III or V-VI, one species from the antigen/target protein group must be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. O'Laughlin-Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

Bridget O'Laughlin-Bunner
Art Unit 1647
August 31, 2000

ELIZABETH KEMMERER
PRIMARY EXAMINER